[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Bispecific Chimeric Antigen Receptors to CD22 and CD19 for Treating Hematological Cancers

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins that have antibody binding fragments fused to protein signaling domains that activate T cells. The antibody binding fragments allow the CAR to recognize specific cell types, thereby activating the T cell through the protein signalling domain. Once activated, the T cells selectively eliminate the cells which they recognize. By engineering a T cell to express CARs with antibody binding fragments which are specific for cell surface proteins that are associated with diseased cells, it is possible to treat the disease. This is a promising new therapeutic approach known as adoptive cell therapy.

CD22 and CD19 are cell surface proteins that are expressed on a large number of B cell lineage hematological cancers, such as leukemia and lymphoma. CD19 CAR T cells have demonstrated potent activity against leukemia in early clinical trials. However, some of these patients will relapse with leukemia that no longer expresses the CD19 protein. This technology concerns the use of two high affinity antibody binding fragments as the targeting moieties of a CAR: one to CD22 (m971), and one against CD19 (FMC63). The resulting CAR can be used in adoptive cell therapy treatment for cancers which express either CD22 or CD19.

Potential Commercial Applications:

• Treatment of diseases associated with increased or preferential expression of CD22 or CD19.

• Specific diseases include hematological cancers such as chronic lymphocytic leukemia (CLL), hairy cell leukemia (HCL) acute lymphoblastic leukemia (ALL) and lymphoma.

Competitive Advantages:

• High affinity of the m971 and FMC63 antibody binding fragments increases the likelihood of successful targeting.

• Targeted two antigens expressed on the same type of diseased cells may increase efficacy relative to targeting a single antigen.

• Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients.

• Hematological cancers are susceptible to cytotoxic T cells because they are present in the bloodstream.

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventors: Terry J. Fry, et al. (NCI)

Publications:

1. Haso W, et al. Anti-CD22-chimeric antigen receptors targeting B-cell precursor acute lymphoblastic leukemia. Blood. 2013 Feb 14;121(7):1165-74. [PMID 23243285]

2. Lee DW, et al. T cells expressing CD19 chimeric antigen receptors for acute lymphoblastic leukaemia in children and young adults: a phase 1 dose-escalation trial. Lancet. 2015 Feb7;385(9967):517-28. [PMID 25319501]

Intellectual Property: HHS Reference No. E-106-2015/0-US-01 - US Provisional Application No. 62/135,442 filed March 19, 2015

Related Technologies:

• HHS Reference No. E-080-2008/0-US-03 - US Patent Application No. 12/934,214 filed September 23, 2010

• HHS Reference No. E-291-2012/0-PCT-02 - PCT Application No. PCT/US2013/060332 filed September 18, 2013

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov

Magnetic Resonance Magnification Imaging

Description of Technology: With conventional MRI, it is inherently time-consuming to generate high dimensional images with high spatial resolution. This invention, inspired by optical magnification, uses a fundamentally different approach to MRI image formation. It uses specially designed radiofrequency pulses to interact with the magnetic field gradient, wherein the region of interest is filled with more pixels resulting in increased spatial resolution and reduced overall scan times for patients at the region of interest. Currently, 3-fold magnification has been achieved *in vivo*. This invention allows the magnification of predefined regions of interest and improved diagnostic images for the same scan time.

Potential Commercial Applications:

• Diagnostic imaging

• Environmental Sampling/Testing

• Quality Control/Quality Assurance

Competitive Advantages:

• Magnified image with increased image resolution

• A 3-fold increase in spatial resolution in vivo in comparison to traditional MRI scans

• Reduced scan time

• Patient friendly - with reduced scan time, there is less patient discomfort especially for those who experience claustrophobia

Development Stage:

• Early-stage

• In vivo data available (animal)

Inventor: Jun Shen (NIMH)

Intellectual Property: HHS Reference No. E-252-2014/0 - US Provisional Application No. 62/059,520 filed October 3, 2014

Licensing Contact: Jennifer Wong, M.S.; 301-435-4633; wongje@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Mental Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Magnetic Resonance Magnification Imaging. For collaboration opportunities, please contact Jun Shen at shenj@mail.nih.gov or 301-451-3408.

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Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health

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